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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,154	10/04/2001	Toyohide Shinkawa	249-201	9598

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EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
970,154	SHINKAWA et al
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 7/29/04.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-21 is/are pending in the application.

Of the above claim(s) 18-21 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Claims 1-21 are pending.

Applicant's election without traverse of Group I (claims 1-17) in the reply filed on 7/29/04 is acknowledged.

The disclosure is objected to because of the following informalities: at page 2, third full paragraph, "sepharose" should commence with a capital; at page 4, sixth full paragraph and page 14, fifth full paragraph –concanavalin—has been misspelled; at page 34 "(1) fractionation of an antibody comprising" is incomplete, because it does not state what the antibody "comprises".

Appropriate correction is required.

Claim 4 is objected to because of the following informalities: in claim 4 – concanavalin – has been misspelled.

Appropriate correction is required.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear in setting forth the relationship between the "carbohydrate" and the "antibody". In reading "a carbohydrate binding to the antibody", one could understand this to mean a carbohydrate that is the cognate antigen of the antibody, i.e. the carbohydrate binds noncovalently to the antigen binding site of the antibody; alternatively, one could understand this to mean a carbohydrate that is bound covalently to the constant region of the antibody. It is believed that applicant intends the latter – e.g. pages 11-12. On the other hand, one could reasonably contemplate that applicant

intends the former from the fact that applicant considers the term "antibody" as encompassing numerous fragments which have one or more antigen binding sites, but no Fc region – e.g. the Fab fragment and numerous other fragments recited thereafter at page 15, fourth paragraph.

Each of claims 1 and 8-13 are unclear by reciting "using a substance" or "using a column", etc. without reciting an active verb step that states that the "substance" or the "lectin" binds to a certain carbohydrate structure of an antibody composition and that the thus bound or unbound fraction of the antibody composition is recovered as the purified antibody composition having the desired property.

In this regard, the examiner notes that claims 1 and 10-11 would be interpreted, at the best as one can understand, to mean that one recovers the fraction of the antibody composition that binds to the "substance" or "lectin"; however, the examiner notes that, in example 1, applicant recovers the non-binding (non-adsorbed) fraction, as the fraction having the desired property (ADCC). The examiner considers that claim and 10-11 fail to clearly encompass the purification process of example 1.

Claims 5 and 8-9 are each unclear by reciting "lens culinaris lectin E4." One would not know what this is, since the specification teaches a "Lens culinaris" lectin and a "phaseolus vulgaris lectin E4" but no "Lens culinaris lectin E4" (see page 14).

Claims 1-3, 6-7 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. Applicant has not adequately described the genus of substances "having an affinity to a carbohydrate".

While one of skill could reasonably envision lectins and antibodies directed to carbohydrates, one of skill could not envision other members of the genus. Applicant's disclosure refers to a subgenus of "low molecular weight compounds" (pages 13 and 15-16); beyond serotonin and phenyl borate (recited at page 15), one has no idea what the other members of this subgenus might be; after these recited members, applicant has recited or "the like"; however one does not know what makes a compound "like" serotonin or phenyl borate, since these two "low molecular weight compounds" have no common structural features that would define the subgenus.

Applicant also considers a "functional group having affinity for a carbohydrate "to be a "hydrophobic functional group" (page 16, lines 8-10); however applicant considers that an antibody having a high sugar content is more hydrophobic than one with low sugar content (page 16, lines 4-8).

Thus a hydrophobic functional group does not truly have affinity for a carbohydrate.

Claims 1-3, 6-7 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for processes using a "substance having an affinity to a carbohydrate" that is limited to a lectin or an antibody specific for a carbohydrate, does not reasonably provide enablement for other such "substances" such as "low molecular weight compounds". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

practice the invention commensurate in scope with these claims. As noted supra applicant has not given an adequate description of the genus of the "substances" having the required affinity. In such case, the claimed invention is not enabled. See Fiers v. Sugano 25 USPQ 2d at page 1606.

Claims 1-2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Dobre et al (Jour Immunol meth 59,339,1983.

Dobre et al show the fractionation of rabbit IgG on a Con A-sepharose 4 B column. The Con-A retained fraction has a higher affinity for Fc receptor bearing macrophages, than does the unfractionated IgG. This affinity for macrophages is a "desired property" since macrophages with antibody bound to Fc receptors can participate in an activity such as ADCC – e.g. see specification pages 16-17. From the above claims, 1 and 4-6 are anticipated. Claim 2 is included since applicant has disclosed that Con-A binds N-glycan (page 14); thus the use of Con-A by Dobre et al inherently accomplished what is recited.

Claims 1-2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Peng et al (Vet Immunol and Immunopathol 36, 83, 1993).

Peng et al teach the fractionation of dog serum on a Con-A sepharose column. The column binds dog IgE well, and the elution of IgE therefrom can be used as a preparative technique for dog IgE (page 87, second full para and page 88, first full para.). It is properly considered that being of the class IgE is a "desired property" since it is of interest to obtain dog IgE and study its properties (page 88).

Claims 1-2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyle et al (Jour Immunol meth, 32, 51, 1900 in light of Turner et al (5,455,332).

Boyle et al show purification of a rabbit antiserum on protein A Sepharose (a bacterial lectin as shown by Turner et al at col.3, lines 50+) or on Con-A Sepharose. This provides for the separation of IgG and IgM class antibodies, which are the desired antibody classes for the preparation of IgG and IgM sensitized sheep erythrocytes. See abstract, Table 1, and discussion. Claim 2 is included since Con-A inherently binds to N-glycan (instant page 14).

Claims 1-6, 8, 10 and 15 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Adams et al (WO 99/10494 or US 6,342,220) in light of Turner et al (5,455,332).

WO and US documents are equivalent; the examiner will refer only to the US document. Adams et al teach separation of antibody products via affinity chromatography on protein A Sepharose (protein A is a bacterial lectin, as evidenced by Turner et al at col.3, lines 50-56), on lentil lectin Sepharose, on wheat germ agglutinin Sepharose, and or Con-A Sepharose. See col.23, lines 56+ and col.36, lines 50+. Use of protein A would obtain antibodies of a desired class (e.g. see Tuner et al at col.3, lines 54+). Use of lentil lectin, WGA or Con-A would obtain antibodies having "homogeneity of the carbohydrate structure of the antibody" (considered instantly as a "desired property" at page 17, lines 4-5). From these considerations instant claims 1 and 4-6 are anticipated.

Regarding claim 2, the Con-A inherently binds to an N-glycan (see instant page 14).

Concerning claims 3 and 8, the WGA inherently binds to N-acetylglucoseamine on an N-glycan (instant page 14).

Regarding instant claims 3 and 10, the lentil lectin (LCA) inherently binds to fucose on an N-glycan (instant page 14).

Regarding claim 15, Adams et al teach that one a more of the taught processes may be used (col.23, line 55).

Claims 12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bridonneau et al (J. Chrom; 616, 197, 1993) in light of Wright et al (Trends in Biotech; 15, 26, 1997). Bridonneau et al teach that pooled human IgG (containing classes IgG1, IgG2, IgG3 and IgG4) can be separated on an octyl sepharose column (page 202). The non-adsorbed fraction is enriched for the IgG2 subclass. Wright et al (p.30) teach that the IgG2 subclass of human IgG differs in its galactose distribution from other subclasses. Thus the method of Bidonneau et al inherently provided for a non-adsorbed fraction that differed in its galactose content from that of the adsorbed fraction.

The above is sufficient to anticipate instant claims 12 and 16.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is

571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

Saunders/tgd

October 19, 2004